

19. (Four Times Amended) A method of delivering a medicament comprising the steps of:

En providing a chewing gum consisting of ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, flavors, and at least one medicament, the ingredients and medicament being uniformly distributed throughout the chewing gum, the chewing gum including less than the typical amount of medicament that is swallowed by the individual to achieve an effect; and

chewing the chewing gum for at least 2 minutes in a buccal cavity of an individual chewing the chewing gum.

REMARKS

This response is submitted in response to the Office Action mailed on October 18, 2002. The Office Action rejects Claims 1-4, 6-11, 19, 20, and 22 under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent No. 5,013,716 (*Cherukuri*). In addition, the Office Action further rejects Claims 5, 12, and 21 under 35 U.S.C. § 103(a) as being unpatentable over *Cherukuri*, and rejects Claims 1, 7, and 19 under 35 U.S.C. § 103(a) as unpatentable over *Cherukuri* in view of U.S. Patent No. 5,922,347 (*Hausler*). In response, Applicants have amended Claims 1 and 19. Applicants respectfully submit that in view of the Amendment the rejections have been overcome and therefore request that they be withdrawn.

The present invention provides methods for delivering a medicament to an individual. The methods include the steps of providing a chewing gum consisting of ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, and flavors, and at least one medicament. The chewing gum includes less than the typical amount of medicament that is swallowed by an individual to achieve an effect, and the ingredients and medicament are uniformly distributed throughout the gum. The gum is chewed causing the medicament to be released from the chewing gum composition into the buccal cavity of the individual. Continuous chewing creates a fluid pressure causing the

medicament to enter the systemic system of the individual through an oral mucosa of the individual.

The invention also provides a method for reducing the amount of agent necessary to achieve an effect in an individual as compared to a typical agent that is swallowed. The method includes the steps of providing a chewing gum consisting of ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, flavors, and at least one agent that is typically swallowed by an individual to achieve a specific effect. The ingredients and agent are uniformly distributed throughout the chewing gum. The chewing gum includes less than the typical amount of agent that is swallowed by the individual to achieve the effect. The chewing gum is chewed thereby causing the agent to be released into the saliva of the individual. Continuous chewing forces the agent through an oral mucosa contained in a buccal cavity of the individual.

The invention further provides a method of delivering a medicament comprising the steps of providing a chewing gum consisting of ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, flavors, and at least one medicament, the chewing gum including less than the typical amount of medicament that is swallowed in order to achieve a desired effect. In addition, the ingredients and medicament are uniformly distributed throughout the chewing gum. The method also includes chewing the chewing gum for at least 2 minutes in a buccal cavity of an individual chewing the chewing gum.

Claims 1-4, 5, 6-11, 12, 19, 20, 21 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Cherukuri*. Applicants respectfully submit this rejection is not proper.

As is clear from the claims, the present invention is directed to methods not compositions. The Applicants are not attempting to claim "properties" of prior art products or compositions as argued by the Examiner, but specific steps of a series of methods. See Office Action at 3. Therefore, the Best case cited by the Examiner is clearly inapplicable.

While it may be arguable that *Cherukuri* discloses a chewing gum having ingredients similar to Applicants, there is no mention or suggestion for using this composition in the specific manner set forth in the claims. For example, there is absolutely no teaching or suggestion in

Cherukuri of a method for delivering a medicament that involves using less than the typical amount of agent that is swallowed by an individual to achieve a desired effect. In fact *Cherukuri* specifically states that the amount of medicament used in general is “the ordinary dosage required to obtain the desired result.” See col. 7, lines 10-15, thus clearly teaching away from the present invention where less than the ordinary amount is used. Moreover, the cited reference is devoid of any mention to use an amount lower than the normal amount to achieve a desired effect.

In addition to the above, *Cherukuri* does not disclose or remotely suggest a method of delivering a medicament which includes the step of chewing gum for at least two minutes, as set forth in Claims 2 and 19. *Cherukuri* is completely silent as to any methods of using chewing gum composition or methods of chewing gum for at least two minutes to deliver a medicament. The Patent Office states that it would have been *prima facie* obvious, but provides absolutely no evidence or reasoning for this blank assertion. It is established law that conclusory statements such as the one provided here are insufficient basis for maintaining an obviousness rejection. See In re Sang-Su Lee, 277 F.3d 1338, 61 USPQ 2d 1430 (Fed. Cir. 2002). Therefore, since *Cherukuri* clearly does not mention or suggest any of the methods for delivering a medicament to an individual as set forth in the present claims, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

Claims 1, 7, and 19 are rejected as being unpatentable over *Cherukuri* in view of *Hausler*. Applicants respectfully submit that this rejection is not proper.

Hausler does not remedy the deficiencies of *Cherukuri*. As noted above, the present invention is primarily directed to methods not compositions. *Hausler* does not mention or suggest any methods for delivering a medicament in a chewing gum composition that involves using less than the typical amount of agent that is swallowed by an individual to achieve a desired effect. All of the claims in the instant application include this limitation. Accordingly, Applicants respectfully submit that *Hausler* alone or in combination with *Cherukuri* does not render the present invention obvious and this rejection under 35 U.S.C. § 103(a) has been overcome.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend Claims 1 and 19 as follows:

1. (Four Times Amended) A method for delivering a medicament to an individual comprising the steps of:

providing a chewing gum consisting of ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, and flavors, and at least one medicament, the ingredients and medicament having a uniform distribution throughout, the chewing gum including less than the typical amount of medicament that is swallowed by the individual to achieve an effect;

chewing the chewing gum to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual; and
continuing to chew the chewing gum thereby creating a fluid pressure causing the medicament to enter the systemic system of the individual through an oral mucosa of the individual.

19. (Four Times Amended) A method of delivering a medicament comprising the steps of:

providing a chewing gum consisting of ingredients selected from the group consisting of elastomers, resins, fats, oils, softeners, fillers, waxes, colorants, antioxidants, plasticizers, texturizers, emulsifiers, whiteners, acidulants, bulking agents, essential oils, sweeteners, flavors, and at least one medicament, the ingredients and medicament being uniformly distributed throughout the chewing gum, the chewing gum including less than the typical amount of medicament that is swallowed by the individual to achieve an effect; and

chewing the chewing gum for at least 2 minutes in a buccal cavity of an individual chewing the chewing gum.